Position Paper on Food and Drug Administration of the Philippines Center for Drug Regulation and Research and Center for Device Regulation, Radiation Health and Research New Requirement to Obtain Certificate of Medical Device Listing/CMDL for Importation of Clinical Trial's Ancillary Supplies

Background and Introduction

On June 2023, five clinical research organizations and a sponsor have received a notification of deficiency/NOD following the submission of application for their respective clinical trial's import license which is required by the Bureau of Customs to successfully facilitate and clear the importation of study ancillary supplies such as laboratory kits, tablets, and bulk supplies of urine sample collection container, blood collection needle vacutainer, etc.). This directive was recently implemented in reference to and compliance with Administrative Order (AO) No.: 2018-0002 Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements where it states that:

"...medical devices strictly for research, clinical trial, exhibit, and/or donated brand new medical devises are exempted from Notification and Registration. However, the researcher, institution, and/or user of such devices shall apply for a Certificate of Medical Listing (CMDL). And by definition, CMDL, refers to the authorization issued for a medical device that is intended for research, clinical trial, exhibit. Donation, etc. and that is not intended for sale"

Philippine Clinical Research Professionals, Inc. (PCRP) is a non-stock and nonprofit SEC-registered professional organization established in 2001, whose individual and company members are primarily affiliated with clinical trial sponsors and contract research organizations that operate in the Philippines. At present, PCRP membership spans across a total of 30 company members from Sponsors and CROs with a breakdown of 359 individual members. PCRP member companies obtain their License to Operate (LTO) from the Food and Drug Administration of the Philippines (FDA-P). For more than 2 decades now, PCRP has been actively initiating programs and spearheading initiatives that are geared toward harmonization and fit-for-purpose response to the highly dynamic global and local clinical research ecosystem. Part of the notable engagements of the only professional organization of clinical researchers in the country is collaborating with other stakeholders and government agencies such as Department of Health, Food and Drug Administration of the Philippines, Philippine Health Research Ethics Network, Philippine Health Research Ethics Board, DTI Board of Investments, Bureau of Quarantine, Philippine Council for Health Research Development, etc. PCRP believes that it is in the best interest of clinical research players and stakeholders to discuss matters that will have impact on the overall conduct of clinical trials in the country.

PCRP considers itself as an invaluable player to clinical trial conduct, hence we respectfully submit this Position Paper to Food and Drug Administration of the Philippines: Center for Drug Regulation and Research (CDRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR) to communicate PCRP's position to be heard and considered, and to provide meaningful feedback on the concerns raised by CDRR and CDRRHR on requiring clinical trial applicants to perform a separate application of CMDL to CDRRHR for "bulk supplies and other ancillary supplies" that will be used solely to facilitate the conduct of an FDA of the Philippines approved drug/biologic/vaccine clinical trials.

Impact of New Directive Mandating Sponsors and CRO to Apply and Obtain CMDL for Ancillary Supplies for Use in Drug/Biologic/Vaccine Clinical Trials

PCRP believes that the new directive poses a significant impact both on short- and long-range operationalization and governance of both current and future studies, creating an undesirable ripple effect on upcoming international collaborative research in the Philippines. These ongoing studies were granted approvals by the Philippine FDA and to some extent by the Single Joint Research Ethics Board (SJREB) as well as by the local Research Ethics Committee (REC) where the clinical studies are conducted.

In a survey initiated and launched by PCRP on 19 June 2023, all member companies were sent with a Google Survey asking the Country Heads to answer the following questions:

- 1. Estimate number of ongoing studies that are approved by REC and FDA of the Philippines;
- 2. Estimate number of upcoming/new studies with application for submission to and review/approval by REC and FDA of the Philippines;
- 3. Average number of months for receiving approval from FDA of the Philippines, including initial import license;
- 4. Average number of months for receiving approval of import license amendment from FDA of the Philippines

A total of 10 respondents have participated and shared their company data for the calendar year – Year-To-Date/YTD 2023.

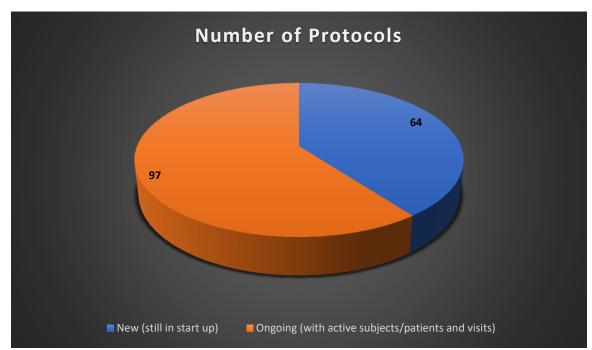


Figure 1: Number of New and Ongoing Protocols Among PCRP Member Companies

PCRP also believes that multilateral discussions through dialogue, forum or consultation meeting with key players and stakeholders should be an essential and integral process and critical component during adoption triggered by policy change, or more so in this case which will cause a huge impact to patients/clinical trial participants, investigators, clinical trial sites and sponsors.

Discussion Points

The list of ancillary materials needed for the proper execution of clinical trials is extensive and only growing as trials become more complex and time-sensitive which include all materials required to conduct a clinical trial beyond the experimental drug and the comparator drug, if relevant, simple medical supplies, such as syringes, swabs, surgical knives, gloves, diluents, medical devices, diagnostic and testing equipment, centrifuges, computers, eDiaries, and temperature-control equipment, such as water baths and freezers and any other items that the patient and medical practitioner need to administer the drug and evaluate the safety and efficacy parameters under investigation (Outsourcing Pharma, 2022).

PCRP believes that mandatory requirement to apply and secure for a separate CMDL from import license for bulk items and other ancillary supplies will lengthen

^{*}Data from 19 June 2023 PCRP survey among member companies

the already non-competitive start up timeline of Philippines that is averaging 6-8 months, thus making our country even more unattractive to global sponsors. Most of all, shortened timeline approach is patient-centered as it will make the access to the new and novel medicines readily available for patients who are looking for other options for their conditions.

Several countries within Asia have worked to improve their regulatory and clinical trial approval processes and speed, addressing time delay-causing hurdles (Yuvraj, 2019).

- India: The Drug Controller General of India's Apex Committee outlined four major changes in June 2017 to current regulatory process, streamlining it and significantly shortening timelines. Global clinical trial applications and reviewed are expected to be shortened to just 3 – 5 months. Only investigational products require import license.
- Malaysia: Ethics Committee review timelines from the date of submission have been reduced from 70 business days to 50. Import license for investigational products are applied to and obtained from National Pharmaceutical Regulatory Agency (NPRA) while for the ancillary supplies, application is directed to Medical Device Authority (MDA) with similar processing timelines of 5 – 7 working days.
- Singapore: The Singaporean government has simplified its clinical trial approval process, reducing the review of Clinical Trial Notifications to just 5 working days. Importation for investigational products and ancillary supplies are to be notified only through Clinical Research Material (CRM) of Health Sciences Authority
- Taiwan: Taiwan has reduced its review timelines for First In Human clinical trial applications from 120 days to just 30 business days. A fast track route for importation of ancillary supplies is offered for "regulatory compliant" CRO or Sponsor where import license is no longer required. However, import license for investigational products for drug/biologic/vaccine trials is required; similarly, for medical device studies, import license is also mandatory.

The items listed under ancillary supplies for importation will be utilized solely for the conduct of the clinical trial and not the subject of the clinical research study.

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Actual Prescribed
Initial Amendment

Figure 2: Number of Months to Obtain Import License for Initial and Amendment Submission

PCRP reiterates that the ancillary supplies for drug/biologic/vaccine study are materials and tools needed for sample collection and test procedure that are prescribed by the study protocol. The collected biological specimens and patient/clinical trial participant information are going to be processed and analyzed in a central laboratory or centralized service provider authorized and engaged by the sponsor. With these clarifications, drug/biologic/vaccine study protocols are clearly delineated from that of medical device studies that ultimately requires CMDL for the purpose of importation because the current regulations on medical device studies do not warrant submission for review and approval of medical device protocols at the level of FDA-P CDRRHR.

PCRP also believes that standard application of the referenced AO 2018-0002 would mean that CMDL is also required for and applicable to all imported laboratory kits (lab kits) because the typical contents of these kits can also be considered as medical device which will translate to having an added layer of

^{*}Data from 19 June 2023 PCRP survey among member companies

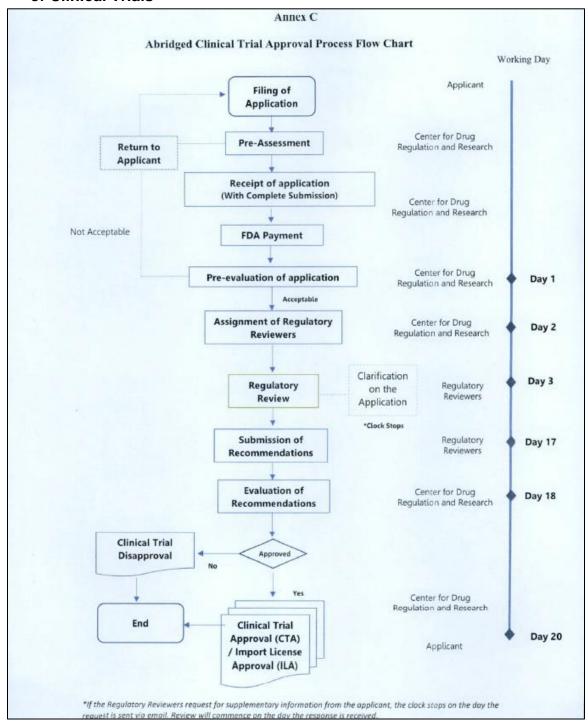
process and protracted timelines with regulatory processes of clinical trials in the Philippines.

Additional days/weeks of impact on 20/30/60-day regulatory timeline from submission to approval.

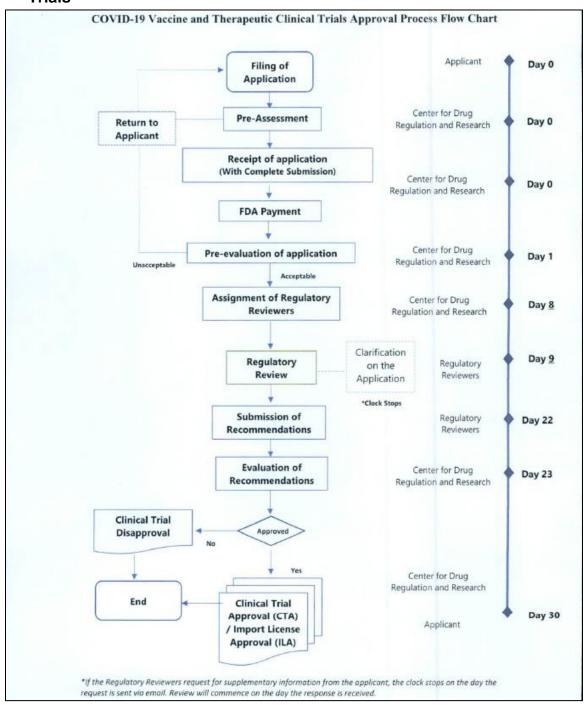
According to the existing regulations from Food and Drug Administration of the Philippines, Center for Drug Regulation and Research, the overall timelines from the time that the initial clinical trial application was submitted until release of approval letter with import license will vary from 20 to 30 to 60 days. For studies that are eligible under FDA Circular 2023-004 Guidelines on Regulatory Reliance on the Conduct of Clinical Trials, release of clinical trial approval and import license is expected on Day 20. Whereas clinical research protocols that involve therapeutic and vaccine against COVID-19, the timeline for receipt of clinical trial approval and import license is on Day 30 according to FDA Circular No. 2020-029-A Amendment to FDA Circular No. 2020-029 entitled Guidelines on Applications for the Conduct of COVID-19 Clinical Trials. Finally, the Administrative Order 2020-0010 Regulations on the Conduct of Clinical Trials for Investigational Products is applicable to research protocols that do not meet the requisites for first two FDA circulars, with an explicit timeline of 60 days for the issuance of regulatory approval letter and import license. These reference regulatory policies concerning the conduct of clinical trials in the Philippines were developed and implemented consistent with the aim of RA No. 11032 or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" which is to create a streamlined, clear, simplified and transparent regulation, boost local competitiveness and attract more local and foreign entrepreneurs.

PCRP supposes that an added layer within the existing process flow FDA Circular 2023-0004, FDA Circular No. 2020-029-A and Administrative Order 2020-0010 will translate to increasing the required timelines for getting the regulatory approval letter and import license, thus, warrants clarifications on the realistic timelines prescribed in these referenced administrative order and circulars. Additional number of days, weeks or months will run against the government agency's intention to enforce the Ease of Doing Business and Efficient Government Service Delivery Act of 2018.

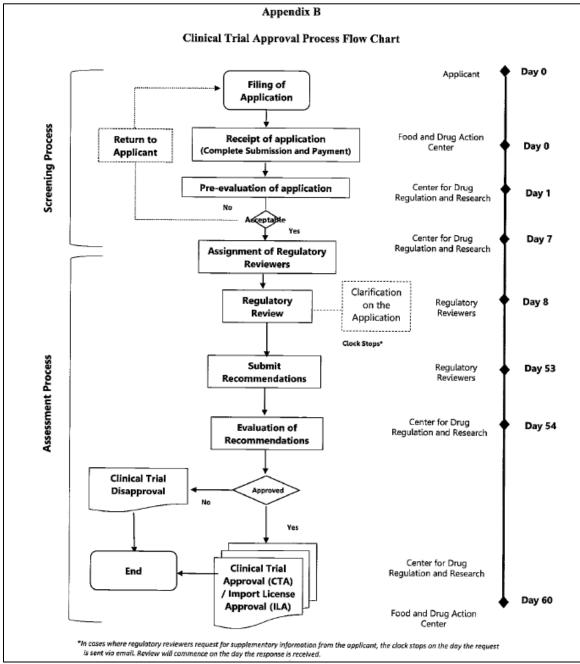
1. FDA Circular 2023-004 Guidelines on Regulatory Reliance on the Conduct of Clinical Trials



2. FDA Circular No. 2020-029-A Amendment to FDA Circular No. 2020-029 entitled Guidelines on Applications for the Conduct of COVID-19 Clinical Trials



3. Administrative Order 2020-0010 Regulations on the Conduct of Clinical Trials for Investigational Products



PCRP also believes that with the involvement of CDRRHR in clinical trial process flow of CDRR for studies involving drug, biologic and vaccine, additional human resources within the government agency is paramount to efficiently support the relevant tasks and activities, otherwise, the delivery process and timeline will be greatly impacted that will lead to further delay in the Philippines Study Start Up

(SSU) timelines. Global sponsors intently look at the country's SSU timelines as a reliable indicator of trial success.

Sourcing of ancillary supplies for clinical trials has become a global challenge since the start of COVID-19 pandemic.

With the surge in number of clinical trials that were initiated at the height of the COVID-19 pandemic which was further confounded by the dwindling supply of raw materials that are used to manufacture the ancillary supplies resulted to global shortage. The main negative impact of supply chain issues and higher demand for products was longer lead times on some of the standard ancillaries they use, such as syringes and IV bags which could range from few weeks to a few months (Earls, 2022). Central laboratory vendors have been continuously updating the contents of the laboratory kits due to limited production and short expiry period of the assembled laboratory supplies.

PCRP considers the additional timeline imposed by CMDL application for ancillary supplies as a confounding variable that could lead to shortage of this vital conduit between the investigational product and patient. Lack of timely ancillary supplies delivery and re-stocking at site will have serious implications on the overall conduct of the study, including patient's/clinical trial participant's safety as it could mean repeated protocol deviations/violations. With the current and projected number of clinical trials in the country at 97 and 64 respectively, we assume that import license amendment application may range between 1 – 3 times for the entire duration of the study. This would mean around 161 – 483 applications will need to be accepted and processed by CDRRHR without undue delays.

PCRP would like to extend its appreciation for the opportunity and time given to us to convey our collective stance through this Position Paper. We continue to affirm that PCRP remains to be your valuable partner and a supportive stakeholder of Food and Drug Administration of the Philippines programs, policies, and initiatives. As an interdependent and partner clinical research stakeholders, we all aspire and work hard toward ethical, risk-based, scientifically robust, efficient and streamlined study conduct of clinical trials in the Philippines. It is our hope and desire that we continue to engage in a meaningful dialogue on important directives before its implementation to give us all a platform to listen, understand and arrive at a consensus that will ultimately benefit our Filipino research participants and sustainability of evidence- based and scientific research. We all heed to the call of innovating systems, processes and practices in doing clinical trials so that our country will continue to be relevant and highly competitive. These are the excellent

characteristics of a flourishing clinical research ecosystem within a country that benefit the Filipino people.

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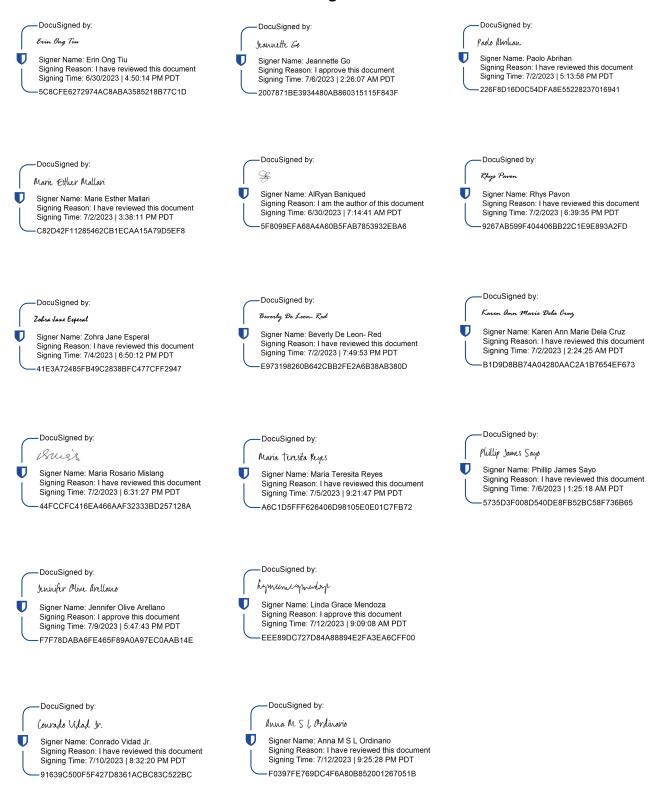
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	9267AB59-9F40-4406-BB22-C1E9E893A2FD	
	Using IP Address: 124.219.44.195	
	Osing ii / Address: 124.210.44.100	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I have reviewed this document	
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Rodmar Pulido		Sent: 6/30/2023 7:12:20 AM
rcpulido@pivot-cro.com		
Security Level: Email, Account Authentication (Required)		
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Rowena Miranda		Sent: 6/30/2023 7:12:20 AM
wengmiranda2012@gmail.com		
Security Level: Email, Account Authentication (Required)		
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Zohra Jane Esperal		Sent: 6/30/2023 7:12:18 AM
zohrajane.esperal@iqvia.com	Zohra Jane Esperal	Viewed: 6/30/2023 6:50:43 PM
Security Level: Email, Account Authentication (Required)		Signed: 7/4/2023 6:50:18 PM
	Signature Adoption: Pre-selected Style	
	Signature ID:	
	41E3A724-85FB-49C2-838B-FC477CFF2947	
	Using IP Address: 111.68.44.198	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I have reviewed this document	
Electronic Record and Signature Disclosure: Accepted: 6/30/2023 6:50:43 PM ID: 5a9f1bd1-160b-4a3a-9709-46b6ef175876		

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp	
Envelope Summary Events	Status	Timestamps	
Envelope Sent	Hashed/Encrypted	6/30/2023 7:12:21 AM	
Certified Delivered	Security Checked	6/30/2023 6:50:43 PM	
Signing Complete	Security Checked	7/4/2023 6:50:18 PM	
Payment Events	Status	Timestamps	
Electronic Record and Signature Disclosure			

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- You can access and read this Electronic Record and Signature Disclosure; and
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turing the cou	rse of your rel	ationship wi	th Parexel.		

Signer Events	Signature	Timestamp
Rhys Pavon		Sent: 6/30/2023 7:12:14 AM
rhys.pavon@parexel.com	Rhys Pavon	Viewed: 7/2/2023 6:39:12 PM
PAREXEL		Signed: 7/2/2023 6:39:41 PM
Security Level: Email, Account Authentication	Signature Adoption: Pre-selected Style	
(Required)	Signature ID:	
	9267AB59-9F40-4406-BB22-C1E9E893A2FD	
	Using IP Address: 124.219.44.195	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I have reviewed this document	
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Rodmar Pulido		Sent: 6/30/2023 7:12:20 AM
rcpulido@pivot-cro.com		
Security Level: Email, Account Authentication (Required)		
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Rowena Miranda		Sent: 6/30/2023 7:12:20 AM
wengmiranda2012@gmail.com	Signed by: MirandaWeng	
Security Level: Email, Account Authentication	Project Manager Reason: I have reviewed this document. Data & Time: 12 Jul 2023 02:32 PM +08:00	
(Required)		
Electronic Record and Signature Disclosure: Not Offered via DocuSign	Dotu Sign,	
Zohra Jane Esperal		Sent: 6/30/2023 7:12:18 AM
zohrajane.esperal@iqvia.com	Zohra Vane Esperal	Viewed: 6/30/2023 6:50:43 PM
Security Level: Email, Account Authentication (Required)		Signed: 7/4/2023 6:50:18 PM
	Signature Adoption: Pre-selected Style	
	Signature ID:	
	41E3A724-85FB-49C2-838B-FC477CFF2947	
	Using IP Address: 111.68.44.198	
	With Signing Authentication via DocuSign password	
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	I have reviewed this document	

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp

Electronic Record and Signature Disclosure: Accepted: 6/30/2023 6:50:43 PM ID: 5a9f1bd1-160b-4a3a-9709-46b6ef175876

Signer Name: Conrado Vidad Jr.

Signing Reason: I have reviewed this document Signing Time: 7/10/2023 | 8:32:20 PM PDT 91639C500F5F427D8361ACBC83C522BC

Electronic Signatures

DocuSigned by: DocuSigned by: DocuSigned by: Erin Ong Tin Paolo Abrilian Teannette Go U Signer Name: Paolo Abrihan Signer Name: Erin Ong Tiu Signer Name: Jeannette Go Signing Reason: I have reviewed this document Signing Reason: I have reviewed this document Signing Time: 6/30/2023 | 4:50:14 PM PDT Signing Reason: I approve this document Signing Time: 7/2/2023 | 5:13:58 PM PDT Signing Time: 7/6/2023 | 2:26:07 AM PDT 226F8D16D0C54DFA8E55228237016941 5C8CFE6272974AC8ABA3585218B77C1D 2007871BE3934480AB860315115F843F DocuSigned by: DocuSigned by: DocuSigned by: Rhys Pavon Marie Esther Mallari Signer Name: AlRyan Baniqued Signer Name: Rhys Pavon D Signer Name: Marie Esther Mallari Signing Reason: I am the author of this document Signing Reason: I have reviewed this document Signing Reason: I have reviewed this document Signing Time: 7/2/2023 | 6:39:35 PM PDT Signing Time: 6/30/2023 | 7:14:41 AM PDT Signing Time: 7/2/2023 | 3:38:11 PM PDT 5F8099EFA68A4A60B5FAB7853932EBA6 9267AB599F404406BB22C1E9E893A2FD -C82D42F11285462CB1ECAA15A79D5EF8 -DocuSianed by: DocuSigned by: DocuSigned by: Karen Ann Marie Dela Cruy Beverly De Leon-Red Zohra Jane Esperal Signer Name: Karen Ann Marie Dela Cruz Signer Name: Beverly De Leon- Red U Signer Name: Zohra Jane Esperal Signing Reason: I have reviewed this document Signing Reason: I have reviewed this document Signing Time: 7/2/2023 | 7:49:53 PM PDT Signing Reason: I have reviewed this document Signing Time: 7/2/2023 | 2:24:25 AM PDT Signing Time: 7/4/2023 | 6:50:12 PM PDT E973198260B642CBB2FE2A6B38AB380D -B1D9D8BB74A04280AAC2A1B7654EF673 41E3A72485FB49C2838BFC477CFF2947 -DocuSianed by: DocuSigned by: DocuSigned by: Phillip James Sayo Osuss Maria Teresita Reyes D Signer Name: Phillip James Sayo Signing Reason: I have reviewed this document D Signer Name: Maria Rosario Mislang Signer Name: Maria Teresita Reyes Signing Reason: I have reviewed this document Signing Reason: I have reviewed this document Signing Time: 7/6/2023 | 1:25:18 AM PDT Signing Time: 7/2/2023 | 6:31:27 PM PDT Signing Time: 7/5/2023 | 9:21:47 PM PDT 5735D3F008D540DE8FB52BC58F736B65 44FCCFC416EA466AAF32333BD257128A A6C1D5FFF626406D98105E0E01C7FB72 DocuSigned by: Jennifer Olive Arellans DocuSigned by: П Signer Name: Jennifer Olive Arellano Rodmar Pulido Signing Reason: I approve this document Signing Time: 7/9/2023 | 5:47:43 PM PDT 702B85B4F9DF413.. F7F78DABA6FE465F89A0A97EC0AAB14E DocuSigned by: Conrado Vidad Jr.